



**Scientific Opinion on the substantiation of a health claim related to fat-free yogurts and fermented milks with live yogurt cultures complying with the specifications “fat free”, “low in sugars”, “high protein”, “source of calcium” and “source of vitamin**

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## SCIENTIFIC OPINION

### **Scientific Opinion on the substantiation of a health claim related to fat-free yogurts and fermented milks with live yogurt cultures complying with the specifications “fat free”, “low in sugars”, “high protein”, “source of calcium” and “source of vitamin D” for nutrition claims and maintenance of lean body mass in the context of an energy-restricted diet pursuant to Article 13.5 of Regulation (EC) No 1924/2006<sup>1</sup>**

**EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)<sup>2,3</sup>**

European Food Safety Authority (EFSA), Parma, Italy

#### ABSTRACT

Following an application from Federación Nacional de Industrias Lácteas (FeNIL), submitted pursuant to Article 13.5 of Regulation (EC) No 1924/2006 via the Competent Authority of Spain, the Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to fat-free yogurts and fermented milks with live yogurt cultures complying with the specifications “fat free”, “low in sugars”, “high protein”, “source of calcium” and “source of vitamin D” for nutrition claims and maintenance of lean body mass in the context of an energy-restricted diet. The Panel considers that the food that is the subject of the claim, fat-free yogurts and fermented milks complying with the specifications “fat free”, “low in sugars”, “high protein”, “source of calcium” and “source of vitamin D” for nutrition claims, is sufficiently characterised. The Panel considers that maintenance of lean body mass in the context of an energy-restricted diet is a beneficial physiological effect. No human intervention studies from which conclusions could be drawn for the scientific substantiation of the claim were provided. The Panel concludes that a cause and effect relationship has not been established between the consumption of fat-free yogurts and fermented milks with live yogurt cultures complying with the specifications “fat free”, “low in sugars”, “high protein”, “source of calcium” and “source of vitamin D” for nutrition claims and maintenance of lean body mass in the context of an energy-restricted diet.

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<sup>1</sup> On request from the Competent Authority of Spain following an application by Federación Nacional de Industrias Lácteas (FeNIL), Question No EFSA-Q-2014-00127, adopted by written procedure on 08 December 2014.

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<sup>3</sup> Acknowledgement: The Panel wishes to thank the members of the Working Group on Claims: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Marina Heinonen, Ambroise Martin, Hildegard Przyrembel, Yolanda Sanz, Alfonso Siani, Sean (J.J.) Strain, Inge Tetens, Hendrik van Loveren, Hans Verhagen and Peter Willatts for the preparatory work on this scientific opinion.

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**KEY WORDS**

yogurt, fermented milk, fat-free, low in sugars, source of vitamin D, source of calcium, health claim

## SUMMARY

Following an application from Federación Nacional de Industrias Lácteas (FeNIL), submitted pursuant to Article 13.5 of Regulation (EC) No 1924/2006 via the Competent Authority of Spain, the Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to fat-free yogurts and fermented milks with live yogurt cultures complying with the specifications “fat free”, “low in sugars”, “high protein”, “source of calcium” and “source of vitamin D” for nutrition claims and maintenance of lean body mass in the context of an energy-restricted diet.

The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence.

The food that is the subject of the health claim is fat-free yogurts and fermented milks with live yogurt cultures complying with the specifications “fat free”, “low in sugars”, “high protein”, “source of calcium” and “source of vitamin D” for nutrition claims. The Panel considers that fat-free yogurts and fermented milks with live yogurt cultures complying with the specifications “fat free”, “low in sugars”, “high protein”, “source of calcium” and “source of vitamin D” for nutrition claims are sufficiently characterised.

The claimed effect proposed by the applicant is “help to maintain lean body mass (muscle and bone) in the context of an energy restricted and balanced diet”. The target population proposed by the applicant is overweight or obese adults that are following energy-restricted diets. The Panel considers that maintaining lean body mass in the context of an energy-restricted diet is a beneficial physiological effect.

The applicant identified 98 human publications, including 32 intervention studies, eight observational studies, three meta-analyses of human intervention studies, seven reviews and 48 other studies (studies on bioavailability and mechanistic studies) as pertinent to the claim. Additionally, 17 animal studies and one *in vitro* study were submitted. All human studies were performed with foods which did not comply with the specification of the food which is the subject of the claim.

The Panel notes that no human studies from which conclusions could be drawn for the scientific substantiation of the claim were provided by the applicant.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of fat-free yogurts and fermented milks with live yogurt cultures complying with the specifications “fat free”, “low in sugars”, “high protein”, “source of calcium” and “source of vitamin D” for nutrition claims and maintenance of lean body mass in the context of an energy restricted diet.

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## BACKGROUND

Regulation (EC) No 1924/2006<sup>4</sup> harmonises the provisions that relate to nutrition and health claims, and establishes rules governing the Community authorisation of health claims made on foods. As a rule, health claims are prohibited unless they comply with the general and specific requirements of this Regulation, are authorised in accordance with this Regulation, and are included in the lists of authorised claims provided for in Articles 13 and 14 thereof. In particular, Article 13(5) of this Regulation lays down provisions for the addition of claims (other than those referring to the reduction of disease risk and to children's development and health) which are based on newly developed scientific evidence, or which include a request for the protection of proprietary data, to the Community list of permitted claims referred to in Article 13(3).

According to Article 18 of this Regulation, an application for inclusion in the Community list of permitted claims referred to in Article 13(3) shall be submitted by the applicant to the national competent authority of a Member State, which will make the application and any supplementary information supplied by the applicant available to the European Food Safety Authority (EFSA).

## STEPS TAKEN BY EFSA

- The application was received on 24/02/2014.
- The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence.
- The scientific evaluation procedure started on 13/05/2014.
- On 08/07/2014, the Working Group on Claims of the NDA Panel agreed on a list of questions for the applicant to provide additional information to accompany the application, and the clock was stopped on 11/07/2014, in compliance with Art. 18(3) of Regulation (EC) No 1924/2006.
- On 25/07/2014, EFSA received the requested information as submitted by the applicant and the clock was restarted.
- On 15/10/2014, the Working Group on Claims of the NDA Panel agreed on a list of questions for the applicant to provide additional information to accompany the application, and the clock was stopped on 23/10/2014, in compliance with Art. 18(3) of Regulation (EC) No 1924/2006.
- On 07/11/2014, EFSA received the requested information as submitted by the applicant and the clock was restarted.
- On 08/12/2014, the NDA Panel, having evaluated the data submitted, adopted by written procedure an opinion on the scientific substantiation of a health claim related to fat-free yogurts and fermented milks complying with the specifications "fat free", "low in sugars", "high protein", "source of calcium" and "source of vitamin D" for nutrition claims and maintenance of lean body mass in the context of an energy-restricted diet.

## TERMS OF REFERENCE

EFSA is requested to evaluate the scientific data submitted by the applicant in accordance with Article 16(3) of Regulation (EC) No 1924/2006. On the basis of that evaluation, EFSA will issue an opinion on the scientific substantiation of a health claim related to fat-free yogurts and fermented milks with live yogurt cultures complying with the specifications "fat free", "low in sugars", "high protein", "source of calcium" and "source of vitamin D" for nutrition claims and maintenance of lean body mass in the context of an energy-restricted diet.

<sup>4</sup> Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. OJ L 404, 30.12.2006, p. 9–25.

**EFSA DISCLAIMER**

The present opinion does not constitute, and cannot be construed as, an authorisation for the marketing of fat-free yogurts and fermented milks with live yogurt cultures complying with the specifications “fat free”, “low in sugars”, “high protein”, “source of calcium” and “source of vitamin D” for nutrition claims, a positive assessment of their safety, nor a decision on whether fat-free yogurts and fermented milks with live yogurt cultures complying with the specifications “fat free”, “low in sugars”, “high protein”, “source of calcium” and “source of vitamin D” for nutrition claims are, or are not, classified as a foodstuff. It should be noted that such an assessment is not foreseen in the framework of Regulation (EC) No 1924/2006.

It should also be highlighted that the scope, the proposed wording of the claim, and the conditions of use as proposed by the applicant may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 18(4) of Regulation (EC) No 1924/2006.

## **INFORMATION PROVIDED BY THE APPLICANT**

**Applicant's name and address:** Federación Nacional de Industrias Lácteas (FeNIL), C/ Ayala, 10, 1<sup>º</sup> izda, 28001 Madrid (Spain).

### **Food as stated by the applicant**

According to the applicant, the food for which this health claim is made is fat-free yogurts and fermented milks with live yogurt cultures with added vitamin D and with no added sugars. The health claim of the present application is to be used for yogurts and fermented milks with live yogurt cultures that comply with certain nutritional characteristics, defined in the Annex to Regulation (EC) No 1924/2006:

**Fat-free** – a claim that a food is fat-free, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 0.5 g of fat per 100 g or 100 mL.

**With no added sugars** – a claim stating that sugars have not been added to a food, and any claim likely to have the same meaning for the consumer, may only be made where the product does not contain any added mono- or disaccharides or any other food used for its sweetening properties. Upon a request by EFSA for clarification, the applicant explained that the health claim of the application is to be used for yogurts and fermented milks that are “low in sugars” as defined in the Annex to Regulation (EC) No 1924/2006.

**High protein** – a claim that a food is high in protein, and any claim likely to have the same meaning for the consumer, may only be made where at least 20% of the energy value of the food is provided by protein.

**Source of calcium and source of vitamin D** – a claim that a food is a source of vitamins and/or minerals, and any claim likely to have the same meaning for the consumer, may only be made where the product contains at least a significant amount as defined in the Annex to Directive 90/496/EEC or an amount provided for by derogations granted according to Article 6 of Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods. The dose of calcium was calculated as  $\geq 120$  mg / 100 g solid yogurt and  $\geq 60$  mg/100 g drinking yogurt. The dose of vitamin D was calculated as  $\geq 0.75$  µg/100 g solid yogurt and  $\geq 0.375$  µg/100 g drinking yogurt.

### **Health relationship as claimed by the applicant**

According to the applicant, the advances of the knowledge of overweight and obesity, as well as of their risk factors, indicate that body weight is not the adequate parameter to be targeted by diets. The ideal pattern of weight loss would be to lose fat mass (preferentially visceral fat) while lean body mass (muscle and bone) is preserved. Lean body mass plays a role in several processes related to weight maintenance, as it contributes to basal metabolic rate, glycaemic control, and lipid oxidation. Therefore, the preservation of lean body mass would also help to prevent further weight re-gain. Certainly, many randomised controlled clinical trials have shown that increased intake of dairy products significantly reduces both body fat mass (both total and visceral/abdominal fat) and waist circumference (an indirect measure of abdominal fat), and also significantly increases lean mass (muscle and especially bone mass), compared with controls, whereas the effect of dairy on body weight reduction was not statistically significant in several RCTs. These data have been recently confirmed in two meta-analyses of RCTs that evaluated the effect of dairy consumption on weight and body composition in adults.



## Wording of the health claim as proposed by the applicant

The applicant has proposed the following wording for the health claim: “fat-free yogurts and fermented milks with live yogurt cultures, with added vitamin D, and with no added sugars, help to maintain lean body mass (muscle and bone) in the context of an energy-restricted diet”.

## Specific conditions of use as proposed by the applicant

The applicant has proposed that two servings of 125 g of yogurt per day would help to maintain lean body mass (muscle and bone) in the context of energy restricted diets, but more dairy products (especially milk) and/or other foods with bioavailable calcium, should be consumed to fulfil the corresponding daily recommended amount for this important nutrient. The target population proposed is overweight or obese adults that are following energy-restricted diets.

## ASSESSMENT

### 1. Characterisation of the food

The applicant initially stated that the food that is the subject of the health claim is “fat-free yogurts and fermented milks with live yogurt cultures with added vitamin D and with no added sugars”.

Fermented milk is obtained by fermentation of milk, which may have been manufactured with or without compositional modification. Yogurts are made with the starter cultures of *Streptococcus thermophilus* and *Lactobacillus delbrueckii* sp. *Bulgaricus*, which are well specified by Codex Alimentarius Standard No. 243/2003. Other types of fermented milks can be made with alternate yogurt cultures composed of *Streptococcus thermophilus* and any *Lactobacillus* species. Yogurts and fermented milks contain at least  $10^7$  CFUs of the yogurt starter microorganisms per gram.

The health claim is to be used for yogurts and fermented milks with live yogurt cultures that comply with certain nutritional characteristics, defined in the Annex to Regulation (EC) No 1924/2006 which the applicant purported relevant to the claimed effect:

- Fat-free – the product contains no more than 0.5 g of fat per 100 g or 100 mL.
- With no added sugars – the product does not contain any added mono- or disaccharides or any other food used for its sweetening properties. Upon EFSA’s request for clarification, the applicant indicated that the health claim is to be used for products that are “low in sugars” which means that the product contains no more than 5 g of sugars per 100 g for solids or 2,5 g of sugars per 100 ml for liquids.
- High protein – at least 20% of the energy value of the food is provided by protein.
- Source of calcium and source of vitamin D – a claim that a food is a source of vitamins and/or minerals, and any claim likely to have the same meaning for the consumer, may only be made where the product contains at least a significant amount. The dose of calcium was calculated as  $\geq 120$  mg/100 g solid yogurt and  $\geq 60$  mg/100 g drinking yogurt. The dose of vitamin D was calculated as  $\geq 0.75$  µg/100 g solid yogurt and  $\geq 0.375$  µg/100 g drinking yogurt.

Information about the nutritional composition of different varieties of fat-free dairy products based on food composition databases in several European countries (Spain, Estonia, Iceland, Italy, Norway and Slovakia) has been provided.

The Panel considers that the food, fat-free yogurts and fermented milks complying with the specifications “fat free”, “low in sugars”, “high protein”, “source of calcium” and “source of vitamin D” for nutrition claims, which is the subject of the health claim, is sufficiently characterised.

## 2. Relevance of the claimed effect to human health

The claimed effect proposed by the applicant is “help to maintain lean body mass (muscle and bone) in the context of an energy restricted and balanced diet”. The target population proposed by the applicant is “overweight or obese adults that are following energy-restriction diets”.

Lean body mass can be described as all body tissue except fat storage tissue.

The Panel considers that maintenance of lean body mass in the context of an energy restricted diet is a beneficial physiological effect.

## 3. Scientific substantiation of the claimed effect

The applicant performed a literature search in the PubMed database, using the search terms “weight control” OR “normal weight” OR “normal body weight” OR “weight maintenance” OR “weight management” OR “obese” OR “overweight” AND “dairy” OR “cheese” OR “milk” OR “yogurt”. Then, the same search combination, but including calcium, was also performed. In addition, a manual search was performed among the references cited in published articles. Exclusion criteria covered studies of poor quality or with no adequate design (short duration, without control groups, recording the data with methods not validated, etc.), studies performed in children and adolescents, observational studies and mechanistic studies. The Panel notes that the literature search used by the applicant did not only target food for which the claim was proposed.

The applicant identified 98 human publications claimed as pertinent to the claim. These publications included 32 intervention studies, eight observational studies, three meta-analyses of human intervention studies, seven reviews and 48 other studies (studies on bioavailability and mechanistic studies). Additionally, 17 animal studies and one *in vitro* study were submitted as pertinent to the claim.

Among 32 human intervention studies, 30 were performed with foods such as dairy products, low-fat dairy products, cow milk, soy milk, skimmed milk, calcium, calcium from dairy products, high-calcium milk, calcium citrate, whey protein, calcium and vitamin D, low-fat milk with added vitamin D, milk and yogurt with added calcium, vitamin D3 and vitamin K1 or K2, high-protein diet, alpha-lactalbumin, and milk basic protein. The Panel notes that these studies were performed with foods which did not comply with the specification of the food which is the subject of the claim. The Panel considers that no conclusions can be drawn from these studies for the scientific substantiation of the claimed effect.

Two studies were performed with fat-free yogurts – Yoplait Light and Yoplait Light Thick and Creamy (Zemel et al., 2005, Thomas et al., 2011). Upon a request by EFSA, the applicant provided information on the nutritional composition of the yogurts used in both studies. Yoplait Light Thick and Creamy contains 12.4 g carbohydrates, of which 8.2 g are sugars, 2.9 g proteins, 1.78 µg vitamin D, and 118 mg calcium /100 g of product, and provides 59 kcal (247 kJ)/100 g of product. Yoplait Light contains 9.4 (composition A) or 12.4 g (composition B) carbohydrates, of which 5.9 g (composition A) or 8.2 g (composition B) are sugars, 2.9 g protein, 1.78 µg vitamin D, and 118 mg calcium/100 g of product, and provides 53 kcal (composition A) or 59 kcal/100 g (composition B). The Panel notes that these studies were performed with products which did not comply with the specifications of the food which is the subject of the claim in relation to the nutrition claim “low in sugars”. The Panel considers that no conclusions can be drawn from these studies for the scientific substantiation of the claim.

Eight human observational studies included studies on dairy products, protein-source foods, diluted yogurt (laban), calcium and calcium and vitamin D. Ten meta-analyses, systematic and other reviews were related to dairy products, low-fat dairy products, high-protein low-fat diet, calcium, vitamin D, calcium and vitamin D. The Panel notes that all of these publications referred to foods which did not

comply with the specification of the food which is the subject of the claim. The Panel considers that no conclusions can be drawn from these studies for the scientific evaluation of the claim.

The Panel notes that no human studies from which conclusions could be drawn for the scientific substantiation of the claim were provided by the applicant.

The Panel concludes that a cause and effect relationship has not been established between the consumption of fat-free yogurts and fermented milks with live yogurt cultures complying with the specifications “fat free”, “low in sugars”, “high protein”, “source of calcium” and “source of vitamin D” for nutrition claims and maintenance of lean body mass in the context of an energy-restricted diet.

## CONCLUSIONS

On the basis of the data presented, the Panel concludes that:

- The food, fat-free yogurts and fermented milks with live yogurt cultures complying with the specifications “fat free”, “low in sugars”, “high protein”, “source of calcium” and “source of vitamin D” for nutrition claims, which is the subject of the health claim, is sufficiently characterised.
- The claimed effect is “maintenance of lean body mass in the context of an energy-restricted diet”. The target population as proposed by the applicant is overweight or obese adults that are following energy-restricted diets. Maintenance of lean body mass in the context of an energy-restricted diet is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of fat-free yogurts and fermented milks with live yogurt cultures complying with the specifications “fat free”, “low in sugars”, “high protein”, “source of calcium” and “source of vitamin D” for nutrition claims and maintenance of lean body mass in the context of an energy-restricted diet.

## DOCUMENTATION PROVIDED TO EFSA

Health claim application on fat-free yogurts and fermented milks with live yogurt cultures complying with the specifications “fat free”, “low in sugars”, “high protein”, “source of calcium” and “source of vitamin D” for nutrition claims and maintenance of lean body mass in the context of an energy-restricted diet pursuant to Article 13.5 of Regulation (EC) No 1924/2006 (Claim serial No: 0413\_ES). February 2014. Submitted by Federacion Nacional de Industrias Lácteas (FeNIL).

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## **ABBREVIATIONS**

CFU    colony-forming units